

REMARKS

The foregoing amendments and these remarks are in response to the Office Action dated August 11, 2006. Applicant hereby requests a three month extension of time. Authorization to charge the extension fees to Deposit Account No. 50-0951 is attached hereto.

At the time of the Office Action, claims 1-23 were pending. In the Office Action, objections were raised to the drawings, abstract, specification and claim 3. Claims 1-11 and 13-22 were provisionally rejected on the ground of non-statutory obviousness-type double patenting. Claim 23 was rejected under 35 U.S.C. §102(b). Claims 1-7, 9-13 and 15-21 were rejected under 35 U.S.C. §103(a). The objections and rejections are discussed in more detail below.

I. Priority

With respect to the claim of priority, Applicant notes that the priority document should have been transmitted to the USPTO by WIPO. During a discussion with Kendra Waterman on February 6, 2007, the Examiner advised that the priority document had not been received and that the Applicant is expected to provide a copy to the Office. Ms. Waterman advised that Examiner that we were unable to file the document at this time, but we are in the process of obtaining the certified copy of the priority document and would submit it as soon as possible.

II. Objections to the Abstract and Specification

In the Office Action, the abstract was objected to because it was alleged to refer to purported merits or speculative applications of the invention, and because it was more than 150 words. The specification was objected to for the informalities listed in the Office. Appropriate corrections are made to the abstract and specification herein, and withdrawal of the objections is thus respectfully requested.

III. Objections to the Drawings

An objection was raised to the drawings for failing to include reference numbers 6 and 11 mentioned in the specification. Also, the drawings were objected to for failing to show every

feature of the invention specified in the claims. More specifically, the intermediate plate element being an open washer integrally formed with a flange portion as stated in claims 8 and 22 and the hole closer to the screw head includes a partial thread as stated in claim 14 were required to be shown or the features cancelled from the claims.

Applicant respectfully submits that the intermediate plate element being an open washer (namely an open ring of metal, which defines a central semi-circular hole) is clearly shown in figures 5, 6, 8 and 9 in connection with the description page 7, line 16 to page 8, line 3. Essentially, the plate shown in figures 5, 6, 8 and 9 may be considered as an open washer integrally formed with a flange portion 21, namely an open ring having an integrally formed flange portion. Also, reference number 6 is already shown in Figure 1 (above and to the left of reference numeral 10), and reference number 11 is added in the attached replacement drawing.

Withdrawal of the objection is thus respectfully requested.

IV. Double Patenting Rejection

Claims 1-11 and 13-22 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2 and 5-16 of copending U.S. Patent Application No. 10/526,366. A terminal disclaimer is filed herewith to overcome the rejection based upon U.S. Patent Application No. 10/526,366. The Commissioner is hereby authorized to charge the terminal disclaimer fee to Deposit Account No. 50-0951.

V. Rejections on Art

Claim 23 is rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 3,709,218 to Halloran (hereafter "Halloran"). Claims 1-7, 9-12 and 15-21 are rejected under 35 U.S.C. §103(a) as being unpatentable over Halloran in view of U.S. Patent No. 6,692,498 to Niiranen (hereafter "Niiranen"). Claim 13 is rejected under 35 U.S.C. §103(a) as being unpatentable over Halloran in view of Niiranen and further in view of U.S. Patent No. 6,270,499 to Leu (hereafter "Leu").

Applicant has amended independent claims 1 and 15 herein to include the subject matter disclosed in previous claims 8 and 22 respectively. Claim 23 is also amended. All independent

claims now recite that the intermediate plate element is an open washer integrally formed with a flange portion.

Applicant notes that a washer is a ring or perforated piece of metal used to give tightness to a joint and therefore an open washer may be considered as an open ring of metal, which defines a central semi-circular hole. As an example, the plate shown in figures 5, 6, 8 and 9, in connection with the description page 7 line 16 to page 8 line 3, may be considered as an open washer integrally formed with a flange portion 21, namely an open ring having an integrally formed flange portion.

When the open washer is placed astride of the locking screw, the locking screw is well accommodated in the central semi-circular hole. In such a manner, the semi-circular profile of the open washer, which defines this semi-circular hole, can embrace the shaft of the locking screw with a continuous contact. This contact between the semi-circular profile and the screw shaft provides high stability of the entire system when the screw is compressed against the plate/open washer. Moreover, the semi-circular profile of the washer permits the introduction of the screw in multiple directions.

Halloran discloses a system that comprises an intramedullary fixation element (21), an intermediate plate element (28), and at least one locking screw (27). The intramedullary fixation element (21) comprises at least one proximal transversal holes (25). The intermediate plate (28) is slightly bent to fit against the bone surface.

It should be noted that Halloran does not disclose that the intermediate plate element comprises a couple of elongated arm portions that are in a position astride of a set screw, wherein intermediate plate is an open washer integrally formed with a flange portion.

Moreover, Halloran overcomes the problem of lack of rotational stability of the intramedullary implant by adding plates on the fracture level. This has nothing in common with the design of the system of the present application. It is clearly shown that the plates in Halloran's patent are on the diaphysis and not on the proximal portion of the bones.

The fracture pattern on the humeral head, or the proximal portion of the humerus, is unique and comprises several fracture fragments. The open washer was specifically designed to accommodate several fracture fragments. It should be noted that, by means of the open washer of the present invention, as mentioned above, there is freedom in the choice of screw directions and

this freedom is suitable for accommodating several fracture fragments on the humeral head or proximal portion of the bone.

On the contrary, the plate of Halloran forces only one screw direction.

For the above reasons, applicant respectfully submits that in Halloran, there is no teaching or suggesting to use a plate having the shape of an open washer, which permits the introduction of the screw in multiple directions.

With regard to Niiranen, it relates to plates independent from nails and therefore has little in common with applicant's claimed invention. Moreover, Niiranen shows only a Y-shaped plate. This Y-shaped plate does not have the same shape and outline of applicant's plate, namely an open washer integrally formed with a flange portion. The Y-shaped plate of Niiranen does not define any central semi-circular hole for the accommodation of the screw, but only a V-shaped seat.

In any case, should the Y-shaped plate be placed astride of a locking screw, the shaft of the locking screw will be placed in the V-shaped seat. This V-shaped seat only provides two points of contact between the plate and the screw shaft, and therefore a stable accommodation of the screw cannot be ensured at all.

As a consequence, the V-shaped seat of Niiranen cannot slide safely on an already inserted screw. Therefore, the Y-shaped plate of Niiranen teaches away from the need for allowing the insertion of an open washer under a locking screw, by sliding the entire plate under the already inserted screw. Moreover, should the Y-shaped plate be placed astride of a locking screw, the V-shaped seat of Niiranen cannot permit at all the stable insertion of a screw in multiple directions, which is required for the use of the system on the humeral head or proximal portion of the bone.

With regard to Lea, this reference shows a locking screw design, which is inserted in the attached piece shown in figure 2 of this patent. Again, this design lacks any flexibility required for treatment of comminuted proximal portion fractures, such as humeral head fractures.


For the foregoing reasons, claims 1, 15 and 23 are believed to be patentable, and in condition for allowance, and applicant traverses the rejections thereof. The dependent claims are believed to be allowable because of their dependence upon an allowable base claim, and because of the further features recited.

VI. Conclusion

Applicants have made every effort to present claims which distinguish over the prior art, and it is thus believed that all claims are in condition for allowance. Nevertheless, Applicants invite the Examiner to call the undersigned if it is believed that a telephonic interview would expedite the prosecution of the application to an allowance. In view of the foregoing remarks, Applicants respectfully request reconsideration and prompt allowance of the pending claims.

Respectfully submitted,

Date: 2-9-07


Mark D. Passler
Registration No. 40,764
AKERMAN SENTERFITT
Post Office Box 3188
West Palm Beach, FL 33402-3188
Telephone: (561) 653-5000